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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/771,057	02/03/2004	Gregory E. Conner	21696/1211949-US2	1518
87155	7590	08/18/2009		
John Storella, P.C. 6451 Hillegass Avenue Oakland, CA 94618			EXAMINER ALSTRUM ACEVEDO, JAMES HENRY	
			ART UNIT	PAPER NUMBER
			1616	
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			08/18/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/771,057	Applicant(s) CONNER, GREGORY E.	
	Examiner JAMES H. ALSTRUM ACEVEDO	Art Unit 1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 June 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 29-52 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 29-52 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>6/26/09</u> . | 6) <input type="checkbox"/> Other: _____ |

Art Unit: 1616

DETAILED ACTION

Claims 29-52 are pending. Applicants previously cancelled claims 3, 12-17, and 20. Applicants have newly cancelled claims 1-2, 4-11, 16-19, and 21-28. Claims 29-52 are new. Applicants amended claim set and remarks/arguments submitted on June 26, 2009 are acknowledged. All rejections not explicitly maintained in the instant office action have been withdrawn per Applicants' claim amendments.

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on June 26, 2009 has been entered.

Claim Rejections - 35 USC § 102

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 29, 31-35, 37-40 are rejected under 35 U.S.C. 102(e) as being anticipated by Bruna et al. (U.S. Patent No. 6,056,169).

Applicant claims an inhaler adapted to deliver an aerosolized composition to a lung of a person, wherein the composition comprises thiocyanate, and wherein the composition intended to be administered from the inhaler may comprise other components (e.g. antifungal, anti-viral, etc.).

Art Unit: 1616

Claim interpretation

The phrase "adapted to deliver an aerosolized composition to a lung of a person, wherein the composition comprises thiocyanate" recites an intended use of the claimed inhaler. An intended use does not modify the claimed inhaler, because it does not impart any structure or require that the claimed inhaler contain any specific composition.

Bruna discloses **an inhaler for dispensing accurate and reproducible doses of powder** (title; abstract; and claims 1-7). Dry powder inhalers are inherently adapted to deliver aerosolized powder to the lungs of a person. It is reasonably assumed that an inhaler adapted to deliver a composition comprising thiocyanate reads on an inhaler adapted to deliver a solid, because thiocyanate refers to an anion. The thiocyanate must be present as a salt and salts are generally solids. Thus, Brunas dry powder inhaler fairly reads on an inhaler adapted to deliver an aerosolized composition comprising thiocyanate. It is noted that Applicant's claims do not require that the inhaler actually comprise thiocyanate, but rather that the inhaler has the capacity to deliver an aerosolized composition comprising thiocyanate.

Response to Arguments

Applicant's arguments with respect to claims 29, 31-35, and 37-40 have been considered but are moot in view of the new ground(s) of rejection.

Claims 30, 36, and 41-52 are rejected under 35 U.S.C. 102(b) as being anticipated by Wetterlin (U.S. Patent No. 4,667,668).

Art Unit: 1616

Applicant claims an inhaler adapted to deliver an aerosolized composition to a lung of a person, wherein the composition comprises hydrogen peroxide, and wherein the composition intended to be administered from the inhaler may comprise other components (e.g. antifungal, anti-viral, thiocyanate, etc.).

Claim interpretation

The phrase "adapted to deliver an aerosolized composition to a lung of a person, wherein the composition comprises hydrogen peroxide" recites an intended use of the claimed inhaler. An intended use does not modify the claimed inhaler, because it does not impart any structure or require that the claimed inhaler contain any specific composition.

Wetterlin discloses **an inhaler for administering a solution of a pharmacologically active compound to a patient as droplets suspended in a propellant** (title; abstract; claims 1-7).

Wetterlin's inhaler is inherently adapted to deliver aerosolized liquid to the lungs of a person. It is reasonably assumed that an inhaler adapted to deliver a composition comprising hydrogen peroxide or a mixture of hydrogen peroxide and thiocyanate reads on an Wetterlin's inhaler adapted to deliver a solution (i.e. a liquid) suspended in propellant (i.e. another liquid), because hydrogen peroxide is a liquid that is typically sold as an aqueous solution. Thus, Wetterlin's inhaler fairly reads on an inhaler adapted to deliver an aerosolized composition comprising hydrogen peroxide and/or hydrogen peroxide combined with other components. It is noted that Applicant's claims do not require that the inhaler actually comprise hydrogen peroxide

Art Unit: 1616

or any specific composition, but rather that the inhaler has the capacity to deliver an aerosolized composition comprising hydrogen peroxide and/or additional ingredients.

Response to Arguments

Applicant's arguments with respect to claims 30, 36, and 41-52 have been considered but are moot in view of the new ground(s) of rejection.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 29, 31-35, and 37-40 are rejected under 35 U.S.C. 102(e) as being anticipated by Slungaard et al. (US 2004/0028749) (IDS).

Applicant's claims have been described above. The claim interpretation described above is applied to the instant rejection.

Slungaard discloses **a bronchial inhaler device comprising an aerosolizable form of a pseudohalide selected from the group consisting of thiocyanate**, isothiocyanate, and salts of isothiocyanate (claims 30-31).

It is noted that Applicant's claims do not require that the inhaler actually comprise thiocyanate, but rather that the inhaler has the capacity to deliver an aerosolized composition comprising thiocyanate.

Art Unit: 1616

Response to Arguments

Applicant's arguments with respect to claims 29, 31-35, and 37-40 have been considered but are moot in view of the new ground(s) of rejection.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 29-52 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-17 of U.S. Patent No. 6,702,998 (USPN '998) in view of Bruna et al. (U.S. Patent No. 6,056,169) or Wetterlin (U.S. Patent No. 4,667,668).

Independent claims 29 and 41 of the instant application, claim inhalers adapted to administer an aerosolized composition comprising thiocyanate (most likely a solid) or hydrogen peroxide (a liquid). The claims of USPN '998 claim a method of treatment comprising

Art Unit: 1616

administration of aerosolized thiocyanate alone or in combination with hydrogen peroxide. To aerosolize thiocyanate, hydrogen peroxide, mixtures thereof, and/or thiocyanate and hydrogen peroxide in combination with other components either a liquid or a solid (e.g. a powder) must have been aerosolized. The claims of USPN '998 lack the recitation of an inhaler. This deficiency is cured in part by the teachings of Bruna and Wetterlin and is necessarily obviously implied by the claimed method of USPN '998. The only conventional means of aerosolizing a solid for administration to a person in need thereof is by using a dry powder inhaler, such as is taught by Bruna. To aerosolize a liquid, one must use either an inhaler, such as taught by Wetterlin, or a nebulizer. Because Applicants' claimed inhaler does not suggest that the inhaler is not suited for the aerosolization of propellant containing formulations, it is reasonable that one could use Wetterlin's inhaler to administer the compositions recited in the claimed methods of USPN '998. Thus, the claims of USPN '998 suggest an inhaler adapted to administer either thiocyanate and/or hydrogen peroxide.

Response to Arguments

Applicant's arguments with respect to claims 29-52 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Claims 29-52 are rejected. No claims are allowed.

Art Unit: 1616

Any inquiry concerning this communication or earlier communications from the examiner should be directed to James H. Alstrum-Acevedo whose telephone number is (571) 272-5548. The examiner can normally be reached on M-F, ~10:00-6:00 and Saturdays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on (571) 272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/James H Alstrum-Acevedo/
Patent Examiner, Art Unit 1616
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